OFFICE OF NEW DRUGS

Good Review Practice: Clinical Review Template

CONTENTS

PURPOSE

- This MAPP and its attachments establish procedures for documenting the primary clinical review of original new drug applications (NDAs), biologics license applications (BLAs), NDA/BLA amendments in response to action letters, and efficacy supplements using good review practices (GRPs) in the Office of New Drugs (OND) in the Center for Drug Evaluation and Research.

- This MAPP is one in a series of MAPPs designed to document GRPs for review staff in accordance with MAPP 6025.1 *Good Review Practices*.

DEFINITIONS

- **Clinical Review:** A comprehensive summary and analysis of the clinical data submitted in support of a marketing application. The clinical review also includes the clinical reviewer's assessment of and conclusions about: (1) the evidence of effectiveness and safety under the proposed conditions of use; (2) the adequacy of the directions for use; and (3) recommendations on regulatory action based on the clinical data submitted by an applicant. The clinical review documents the work and conclusions of the clinical reviewer and cannot be altered after it is finalized.

  The clinical review satisfies the legal and policy requirements for documentation of the review process and completion of the review of clinical data before regulatory action on the application. Final scientific and regulatory determinations on the reviewed application are not necessarily reflected in the clinical review.

- **Clinical Review Template:** A structured outline and annotated table of contents used in the preparation of a clinical review. The clinical review template outlines the organization of content, promotes consistency in the documentation of elements, and provides for ready retrieval of information.

- **Recommendation/Risk-Benefit Analysis (previously referred to as Executive Summary):** A required portion of the clinical review that summarizes the clinical review in concise terms, with a succinct explanation of recommended action from the perspective of the clinical reviewer.

POLICY

- The clinical review template will be used by all clinical reviewers within OND.

- The clinical review template will be used to document primary clinical reviews of all original NDAs and BLAs, NDA/BLA amendments in response to an action letter, and efficacy supplements.

- If necessary, the template may be modified by individual clinical review divisions to accommodate unique application issues or division-specific procedures; however, these modifications must be standardized across the division, documented, processed through a template change control board, and cleared as a revision to this MAPP. This MAPP will be revised to add as an attachment each review division-specific modification to the template.

RESPONSIBILITIES

- The **clinical reviewer will** complete each review of designated submissions using the clinical review template. The clinical reviewer should engage in scientific and regulatory dialogue concerning his or her analyses and conclusions, as well as share a draft review, with the clinical team leader and other clinical supervisors to develop complete and scientifically valid review perspectives. However, the final conclusions and recommendations in the clinical review should reflect the clinical reviewer's own opinion and should emphasize that the conclusions and recommendations are based solely on the review of the clinical portion of the application, not the entire application.

- The **clinical team leader will** promote consistent use of the clinical review template by clinical reviewers. The clinical team leader should engage each clinical reviewer in scientific and regulatory exchanges regarding reviews before finalization of the clinical review. When the clinical reviewer's conclusions and/or recommendations differ from those of the clinical team leader, the clinical team leader should encourage the clinical reviewer to document his or her own conclusions and recommendations in the clinical review. In such cases, the clinical team leader is expected to write his or her own review, noting the reasons for any differences in conclusions and recommendations from those of the clinical reviewer.

- **Division and office directors will** promote consistent use of the clinical review template, provide scientific and regulatory perspective on review issues, and encourage clinical reviewers to document in the clinical review their rationale for their own perspectives. In addition, the division or office director with signatory

authority will write his or her own review, summarizing review of the entire application and the basis for the stated regulatory action.

PROCEDURES

- To document clinical reviews, clinical reviewers will use the clinical review template by following the instructions in the attachments to this MAPP.[1] The template is annotated to provide additional explanations of the content for each heading and subheading.

EFFECTIVE DATE

- This MAPP is effective upon publication.

[1] The most recent version of the template and attachments to this MAPP are on the FDA intranet, on the 21st Century Review page.